HFI-35

m5076n

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124305
Facility ID: 153510
Inspection ID #1535100006

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

January 19, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dirck L. Brendlinger, M.D.
Allison Breast Center at Monument Radiology
7231 Forest Avenue
Suite 102
Richmond, Virginia 23226

Dear Dr. Brendlinger:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on November 17, 2000. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **The results of the weekly phantom quality control tests conducted on the [redacted] machine located in room 1, were not documented for 12 weeks during the 12 months preceding the date of the inspection.**

- **The results of the weekly phantom quality control tests conducted on the [redacted] machine located in room 2, were not documented for five weeks during the 12 months preceding the date of the inspection.**

The specific problems noted above appeared on your MQSA Facility Inspection Report. These problems were identified as Level 1 findings because they identify a failure to comply with a significant MQSA requirement.

The following Level 2 findings were listed on the inspection report provided to you at the close of the inspection:

- **Corrective actions for processor quality control failures were not documented at least once;**

- **Processor quality control records were missing for three consecutive days out of 19 days of operation in December 1999;**

- **[redacted] did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period; and**

- **[redacted] did not meet the requirement of having 40 supervised hours of training in mammography.**

Because of the serious nature of these violations, the FDA and the Commonwealth of Virginia conducted a follow-up investigation on December 13, 2000. An MQSA inspection report was not generated for this investigation, but you were informed at the close of the investigation of the findings.

The investigation revealed the following Level 1 findings:

An FDA and State MQSA inspector reviewed facility phantom images from October 22, 1999 to present for both mammography machines located at the facility. Approximately 56 images from October 1999 to May 2000 for both machines were reviewed with 13 images failing with low fiber, speck and mass scores (facility personnel had given the images a passing score). From May 3, 2000 to June 28, 2000, there was no record that phantom image testing had been performed on the [redacted] machine, therefore images from that period could not be reviewed. From July 2000 to present, approximately 20 [redacted] phantom images were reviewed, with fiber and speck groups receiving a passing score and the masses receiving borderline/fail scores. From May 3, 2000 to the present approximately 30 [redacted] phantom images were reviewed, with low fiber scores and low mass scores;

Phantom QC test results had not been plotted for the two weeks preceding the date of the inspection, weeks beginning November 26 and December 3, 2000, for both the [redacted] and [redacted] machines; and

On March 20, April 18, and April 19, 2000, patient images were processed in the film processor when the processor was out of limits.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent violations of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.

- Each step your facility is taking to prevent the recurrence of similar violations.

In addition, we have discussed these findings from the MQSA inspection with your accreditation body, the American College of Radiology (ACR). After an assessment of the serious problems currently present at your facility, we have determined that the quality of mammography may have been severely affected by these conditions. Therefore, we request that you undergo Additional Mammography Review (AMR) by the ACR. Since we have evidence that image quality problems may extend back to May 1999 (the date of the last acceptable QC phantom image test at your facility), the image quality may have been affected from this date to December 2000. Therefore, we believe that the AMR should cover the time frame from May 1, 1999 to December 13, 2000.

Since we have discussed your facility problems with the ACR, they are aware of our request that you undergo an AMR. Your facility is responsible for the payment of the costs to the accreditation body for the AMR. The accreditation body may require a portion or all of this payment prior to the start of the AMR. You should contact the following individual at the ACR for more information on the AMR at your facility:

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091
1-800-227-6440

Once the AMR has been completed, the ACR should submit a detailed report to the FDA on the review, and we will provide you with a copy at that time. This report would usually include the total number of examinations evaluated by the physician(s), a list of examinations with films showing image quality problems that may need to be repeated, and an overall assessment by the reviewing physician(s) of the quality of mammography from May 1, 1999 to December 13, 2000.

If the AMR indicates that clinical image problems exist that represent a risk to health, FDA may request that your facility submit a proposed plan for patient notification, including a draft letter to referring physicians and/or patients which would be subject to approval by the FDA.

Your response should be submitted to Food and Drug Administration, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Lea Anna Perlas, Radiation Safety Specialist
Bureau of Radiological Health
Division of Health Hazards Control
Department of Health
Main Street Station
1500 East Main, Room 240
Richmond, Virginia 23219

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091